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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MANNE SATYANARAYANA REDDY, SAJIA ESWARAIAH,
MATHAD VIJAYAVITTHAL TRIPPAPNCHAR,
GOVINDAN SHANMUGAM,
MADDIPATLA MADHAVI, and KOLLA NAVEEN KUMAR

Appeal 2009-001215
Application 10/647,449
Technology Center 1600

Decided: March 31, 2010

Before DEMETRA J. MILLS, LORA M. GREEN, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for anticipation and obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The following claims are representative and reads as follows:

1. A compound which is a crystalline Form III of (S)-repaglinide, having an X-ray powder diffraction pattern substantially as shown in Figure 1.

2. The compound of claim 1, having an X-ray powder diffraction pattern, expressed in terms of 2 theta angles, that includes five or more peaks selected from the group consisting of 4.44 ± 0.09, 6.81 ± 0.09, 7.80 ± 0.09, 9.28 ± 0.09, 11.09 ± 0.09, 11.89 ± 0.09, 12.92 ± 0.09, 13.46 ± 0.09, 14.34 ± 0.09, 15.77 ± 0.09, 16.24 ± 0.09, 17.08 ± 0.09, 18.06 ± 0.09, 18.75 ± 0.09, 19.25 ± 0.09, 19.59 ± 0.09, 19.99 ± 0.09, 20.34 ± 0.09, 21.18 ± 0.09, 21.96 ± 0.09, 22.18 ± 0.09, 22.58 ± 0.09, 23.24 ± 0.09, 23.77 ± 0.09, 24.08 ± 0.09, 25.02 ± 0.09, 25.31 ± 0.09, 25.78 ± 0.09, 26.67 ± 0.09, 27.39 ± 0.09, 28.03 ± 0.09, 30.26 ± 0.09, 35.50 ± 0.09, and 38.74 ± 0.09 degrees.

8. A composition comprising (S)-repaglinide as a solid, wherein at least 80% by weight of said solid (S)-repaglinide is in crystalline Form III, which has an X-ray powder diffraction pattern, expressed in terms of 2 theta angles, that includes five or more peaks selected from the group consisting of 4.44 ± 0.09, 6.81 ± 0.09, 7.80 ± 0.09, 9.28 ± 0.09, 11.09 ± 0.09, 11.89 ± 0.09, 12.92 ± 0.09, 13.46 ± 0.09, 14.34 ± 0.09, 15.77 ± 0.09, 16.24 ± 0.09, 17.08 ± 0.09, 18.06 ± 0.09, 18.75 ± 0.09, 19.25 ± 0.09, 19.59 ± 0.09, 19.99 ± 0.09, 20.34 ± 0.09, 21.18 ± 0.09, 21.96 ± 0.09, 22.18 ± 0.09, 22.58 ± 0.09, 23.24 ± 0.09, 23.77 ± 0.09, 24.08 ± 0.09, 25.02 ± 0.09, 25.31 ± 0.09, 25.78 ± 0.09, 26.67 ± 0.09, 27.39 ± 0.09, 28.03 ± 0.09, 30.26 ± 0.09, 35.50 ± 0.09, and 38.74 ± 0.09 degrees.

38. A compound which is an amorphous form of (S)-repaglinide, having an X-ray powder diffraction pattern substantially as shown in Figure 4.

Cited References

The cited references appear on page 3 of the Examiner's Answer.[1]

Grounds of Rejection

1 Claims 38 and 40-48 are rejected under 35 U.S.C.§ 102(b) as being anticipated by Grell et al. US 5,312,924. (Ans. 4.)

2. Claims 1, 34-35 are rejected under 35 U.S.C. § 102(b) as being anticipated by Grell et al. US 5,312,924 (*id.* at 5).

3. Claims 1-2, 4-37, 50-51, 53-54, and 56-57 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Grell et al. US 5,312,924 in view of Grell et al., J. Med. Chem. (Grell 2) and Brittain. (*Id.* at 6.)

4. Claims 8-18 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement" (*id.* at 7).

We select claims 1, 8, and 38 as representative of the rejections before us as Appellants have not argued the claims as to each ground of rejection separately.

FINDINGS OF FACT

The Examiner's findings of facts appear on pages 4-8 of the Answer.

PRINCIPLES OF LAW

"Where . . . the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art

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[1] We refer throughout the Decision to the Corrected Answer dated Dec. 7, 2007 as the Answer.

products do not necessarily or inherently possess the characteristics of his claimed product.... Whether the rejection is based on "inherency" under 35 U.S.C. § 102, on "prima facie obviousness" under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products." *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977)(emphasis added). It has long been established that one cannot avoid anticipation by an earlier product disclosure by claiming the same product more narrowly, that is, by claiming the product as produced by a particular process.

"The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985).

The Examiner bears the initial burden of showing nonenablement. *See In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993). "[E]nablement requires that the specification teach those in the art to make and use the invention without 'undue experimentation.' . . . That *some* experimentation may be required is not fatal; the issue is whether the amount of experimentation required is 'undue.'" *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991) (emphasis in original). Some experimentation, even a considerable amount, is not "undue" if, e.g., it is merely routine, or if the specification provides a reasonable amount of guidance as to the direction in which the experimentation should proceed. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

"[A]s part of the *quid pro quo* of the patent bargain, the applicant's specification must enable one of ordinary skill in the art to practice the full scope of the claimed invention. That is not to say that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art." *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

Anticipation

1. Claims 38 and 40-48 are rejected under 35 U.S.C. § 102(b) as being anticipated by Grell et al. US 5,312,924 (recited on 1449). (Ans. 4.)

2. Claims 1, 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Grell et al. US 5,312,924 (*id.* at 5).

ISSUE

The Examiner finds that Grell teaches the claimed compounds.

Appellants contend that the Examiner has failed to provide evidence that the compound of Grell '924 is amorphous (S)-repaglinide as in claim 38 or crystalline repaglinide as in claim 1.

The issue is: Does the evidence of record support Examiner's finding that Grell '924 anticipates the amorphous (S)-repaglinide as in claim 38 or crystalline repaglinide as in claim 1?

ANALYSIS

The Examiner finds that Grell '924 teaches the composition of claims 1 and 38.

Appellants contend that the Examiner has failed to provide evidence that the compound of Grell '924 is amorphous (S)-repaglinide as in claim 38 or crystalline repaglinide as in claim 1.

We conclude that the Examiner has provided sufficient evidence to shift the burden to Appellants to show that the compounds of claims 1 and 38 are not the compound disclosed in Grell '924.

Claim 38

In particular, with respect to claim 38, the Examiner finds that process of obtaining a non-crystalline solid (amorphous), (S)-repaglinide in Example 12 of Grell '924 (col. 89-90) is the same as that disclosed in the Specification, i.e., dissolving the compound in ethanol and evaporating the solvent. (Ans. 4.) Because the non-crystalline compounds are made by the same process, the Examiner has provided sufficient evidence to shift the burden to Appellants to show that the compound of claim 38 is not the compound disclosed in Grell '924.

Appellants have not provided evidence that the compound of Example 12 of Grell '924 is not the claimed amorphous form of (S)-repaglinide.

Claim 1

The Examiner provides reference evidence that polymorphs are different crystalline forms of the same substance, and finds with respect to the crystalline compound of claim 1, that the x-ray diffraction pattern of Figure 3 of the present application and Figure 4, parts 1 and 2 of Grell '924 are the same and within margins of error of each other. (Ans. 5.)

The Examiner finds that Grell '924

> employed alcoholic solvents as well as haloalkanes in various process of making the product for example: in example 1, col. 16, line 49, tetrachloride was used; in example 2 col. 20, line 33, chloroform was used; in example 3, col. 21, line 40, dichlorobenzene was used; in example 11, col. 32, line 48, ethanol was used. Therefore, both polymorphic forms, how to prepare them, and the different solvent systems are found through out the reference. The species of specific solvents rendered the claims of using haloalkane and alcoholic system prima facie obvious.

(Ans. 11.)

We conclude that the Examiner has provided sufficient evidence to shift the burden to Appellants to show that the compound of claim 1 is not the composition disclosed in Grell '924. (*See, e.g.*,, *In re Grose*, 592 F2d. 1161, 1167 (C.C.P.A. 1979) ("The present record does not support the conclusion that appellants' zeolite and Milton's zeolite R are zeolites having different crystal structures.") In the present case, as in *Grose*, Appellants have not provided evidence that the compound of Figure 4 of Grell '924 is not the crystalline form of (S)-repaglinide of claim 1.

Appellants further argue that the compound of Grell '924 and the claimed compound have different melting points and therefore are different compounds. (App. Br. 7; Reply Br. 3-4.)

The Examiner responds, arguing that "[m]ere difference in physical property is well known conventional variation for the same pure substance" and that the solvent used for preparation, and the degree of purification can have an affect on the physical properties of the product. (Ans. 7, 10.)

The claims do not require a specific amount of crystalline compound or purity of the compound. If the solids or crystals of Grell '924 have even a small portion of the claimed compound in the product, the product is anticipated. Moreover, Appellants have not disputed the Examiner's finding that the degree of purification can have an affect on the physical properties of the product, such as melting point.

Thus, we do not find that Appellants have provided evidence that the compound of Figure 4 of Grell '924 is not the crystalline form of (S)-repaglinide of claim 1.

The anticipation rejections of claims 1 and 38 are affirmed.

Obviousness

3. Claims 1-2, 4-37, 50-51, 53-54, 56-57 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Grell '924 et al. US 5,312,924 in view of Grell et al. J. Med. Chem (Grell 2) and Brittain. (*Id.* at 6.)

For the reasons provided above, we conclude that Appellants have not provided evidence that the compound of Figure 4 of Grell '924 is not the crystalline form of (S)-repaglinide of claim 1.

Anticipation being the epitome of obviousness, the obviousness rejection is affirmed.

Enablement

4. "Claims 8-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement" (*Id.* at 7).

The Examiner argues that "Claims 8-18 are drawn to pharmaceutical composition comprising (S)-repaglinide as a solid wherein at least 80% by weight of said solid (S)-repaglinide is in *crystalline form III*." (*Id.*) The Examiner finds that "[t]he pharmaceutical formulation field is well aware that polymorphs when being formulated into compositions may undergo transformation thus, the particular form may not be the same form after processing, compressing etc. (see Rouhi Chem. Eng. New, see p. 34-35)."(*Id.*) Therefore, the Examiner finds that, "in absence of any description or factual evidence, [as to] how a crystalline form can be maintained in a composition to minimize transformation, no assumption can be made that the meta-stable polymorph will be maintained upon compression, tableting etc." (*id.*).

The Examiner finds that the "specification lacks description and enablement that the pharmaceutical composition contains the claimed "form" without transformation. There is no factual basis provided in the specification as to support the transformation of less than 1-5% as found in claims 9-14." (*Id.* at 8.) The Examiner finds that there is "[n]o description nor enabling support can be found as to how such limited transformation can be operable, i.e. temperature, pressure, carrier, etc. In an article provided by applicants *tricky business,* it was evidenced that maintaining crystals in its desirable form is a tremendous effort. In the instant application, no example was found as to how a value of 80% form III was arrived in any solid

composition; nor was any processing resulted in a composition comprising (S)-repaglinide as a solid wherein at least 80% by weight of said solid is in crystalline form III." (*Id.*)

Appellants contend that:

> The claims contain no limitation requiring that the form be maintained indefinitely, or that it be the only form present, and Appellants submit that it is error to read such a limitation into the claims. The instant specification clearly describes and enables the preparation of compositions comprising crystalline Form III of (S)-repaglinide. (*See, e.g.*, instant specification, pages 15-16, ¶ 0056; pages 21-24, ¶¶ 0062-0073.) Furthermore, the specification clearly describes and enables methods for identifying and monitoring the crystalline form in the claimed compositions before, during and after their preparation. (*See, e.g.*, instant specification, page 16, ¶¶ 0053-0054; page 18, ¶ 0057).

(App. Br. 14.)

We do not find that the Examiner has provided sufficient evidence to support a prima facie case of lack of enablement. We conclude that one of ordinary skill in the art reading the present specification sections mentioned in the quote above would understand how to prepare the claimed compounds.

The rejection of the claims for lack of enablement is reversed.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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